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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/735,325

12/12/2000

Steven S. Hackett

S63.2-9222

4944

490

7590

08/11/2004

VIDAS, ARRETT & STEINKRAUS, P.A.

6109 BLUE CIRCLE DRIVE

SUITE 2000

MINNETONKA, MN 55343-9185

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/735,325	Applicant(s) HACKETT ET AL.	
	Examiner Brian E Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the recitation that the "lubricant application port is connected to a supply of lubricant" is not found in the written disclosure. It is noted where applicant referred the Examiner to in the specification for support of this limitation, however, it is not clear what is meant by the limitation as to how this is achieved. For example, is the "connected supply" the so-called application of a coating of lubricant or does the connection mean by a catheter used to inject the lubricant?

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Blaeser et al. (6168617). The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. Fig. 2 shows a stent delivery system having a catheter **18** with a balloon **22** mounted thereon. It can also be seen there is a stent **48** on the catheter. Blaeser also shows a sheath or sleeve

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28 with an overlay portion that covers the stent. Blaeser additionally teach that the sheath includes a lubricious or slip coating thereon, col. 5, lines 60,61. The coating can be interpreted to be a "supply of lubricant" and since it is on the sheath it can be construed to be "connected" thereto. The sheath also has a cone portion and waist overlay portion at its end. The sheath or sleeve also has at least one port **60**. The port is fully capable of allowing a lubricious substance to pass through it. Also note that Blaeser mentions (col. 5, lines 53,54) that the port is a hydraulic perfusion port which inherently means that a lubricant is connected thereto since hydraulics need lubricants to function smoothly.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savin et al. (4950227) in view of Konya et al. '723. Savin et al. disclose a stent delivery system (Fig. 1) with a catheter having a balloon **14** mounted thereon and a stent **16** on a body portion of the balloon. It can also be seen the stent is held on the balloon by two sleeves (**18, 20**) with each having a stent overlay portion shown by distance **D**. Savin also discloses the sleeves are elastomeric, col. 2, lines 21-22. Savin et al. additionally disclose that a lubricating solution can be used between the balloon and sleeves, col. 4, lines 55-57. However, Savin does not disclose using ports to deliver the lubricating solution. Konya teaches fluid openings or "ports" are in the sleeve to deliver a fluid material to aid in positioning the stent, col. 22 lines 57-61. Konya also shows (Fig. 18)

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that the ports **51** are partially defined by the waist overlay portion. The examiner is interpreting the claimed elements "connected to a supply" in this way: since the application of contrast medium extends across the sleeve, it can be construed to contact or "connect" to the port in the sleeve. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055.

It would have been obvious to one of ordinary skill in the art to use the ports as taught by Konya in the sleeves of Savin et al. to provide application routes to deliver lubrication for removal of the sleeves. Note that contrast media is fully capable of providing lubrication, see Kotula et al. (5569275). Kotula teaches contrast medium acts as a lubrication in a vascular device with a sleeve and coil, col. 7, lines 48,51-56.

Response to Arguments

Applicant's arguments filed 5/14/04 have been fully considered but they are not persuasive. Please note as mentioned above claims are given their broadest reasonable interpretation with respect to the written description, *In re Hyatt*, 211 F.3d 1367, 1372 , 54 USPQ2d 1664,1667 (Fed. Cir. 2000). Since applicant's specification states a layer or coating is applied to the surface of the sleeve, page 5, line 12, the Examiner's interpretation (consistent with the applicant's disclosure) of the prior art as having a layer applied on the sleeve would meet the recitation of being "connected to the port" since it is part of the sleeve.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

TC 3700, AU 3738

Brian Pellegrino

A handwritten signature in black ink that reads "Brian Pellegrino". The signature is written in a cursive, flowing style with a large initial "B" and a long, sweeping underline.